REMARKS

Claim Status

Claims 1, 3 4 and 7-25 are pending in the present application. No additional claims fee is believed to be due.

Claim 1 has been amended to further define the present invention wherein the composition further comprises from about 0.001% to about 5 % of a zinc-containing layered material and from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group. Support for this amendment is found on page 5, lines 1-2 and page 8, lines 16-20. Claim 1 has been further amended to define wherein the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1. Support for this amendment is found in the specification and claims as filed, wherein such ratio is determined by the percentage of surfactant and zinc-containing layered material present in the composition.

Claim 7 is amended for proper claim dependency. This amendment addresses the 35 USC § 112 rejection, second paragraph, of Claims 7 and 8 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully request that the 112 rejection be removed.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC §102(b) Over WO 01/00151 (Gavin et al.)

Claims 1, 3, 4, 7-13 and 18-25 have been rejected under 35 USC §102(b) as being anticipated by International Patent Application No. WO 01/00151 to Gavin et al (hereinafter "Gavin et al.") as evidenced by the Mineral Willemite.

Gavin et al. discloses topical compositions for the treatment of microbial infections on the skin or scalp. Specifically, the composition of Gavin et al. includes from about 0.001% to about 10% by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione, from about 0.001% to about 10%, by weight of the composition, of a metal ion source selected from the group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts,

bismuth salts and mixtures thereof and a topical carrier for the anti-microbial active and the metal salt.

The present invention, as currently amended, is directed to a personal care composition comprising from about 0.001% to about 5% of a zinc-containing layered material; from about 10% to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%. Gavin et al. does not disclose or suggest a zinc-containing layered material having a relative zinc lability of greater than about 15%. The Office Action asserts that the disclosure of Gavin et al. discloses that the zinc salt can be zinc silicate, which is also known as the mineral willemite, and since the Applicant teaches that a non-limited list of natural minerals containing zinc can be obtained synthetically or formed in situ and Gavin et al. discloses zinc silicate, which has the same common formula for the mineral Willemite, then the zinc silicate of Gavin et al. would inherently have the same relative zinc lability.

However, Applicants respectfully point out that zinc silicate, which has the same common formula for the mineral Willemite, is not a zinc containing layered material (i.e. ZLM). . However, it is respectfully submitted that the specification at page 5, lines 11-16 merely discloses that that *many* ZLM's occur naturally as minerals. However, not *all* naturally occurring zinc minerals are layered. As readily recognized by one of skill in the art, zinc silicate, or Willemite, is not a layered material. More specifically, silicates are not exemplified in the present specification because silicates are not layered materials.

Further, as required in the claims, a zinc containing layered material is present. And as taught by the specification, the zinc containing layered material achieves the required relative zinc lability. However, Gavin et al. does not disclose a zinc containing layered material and therefore would not inherently have the same relative zinc lability.

Gavin et al. discloses a myriad of zinc salts, including zinc carbonate and a dozen or so other zinc salts at page 6, lines 1-6 of the reference. In this long list of zinc salts, there is no disclosure or suggestions of basic zinc carbonate or any other zinc containing layered material.

In short, Applicants maintain that personal care compositions comprising zinc-containing layered material as instantly claimed are neither disclosed nor suggested by the disclosure of insoluble particulate zinc carbonate provided among a myriad of zinc salts alluded to in Gavin et al.

When one of ordinary skill in the art compares the composition of Gavin et al. to the instantly claimed invention, the compositions are not comprised of the exact same materials; namely Gavin et al. does not teach or suggest a zinc-containing layered material, such as basic zinc-carbonate or others and would not inherently have the exact same properties as the currently claimed product.

In light of the above remarks, it is requested that the Examiner reconsider and withdraw this rejection under 35 USC §102(b).

Rejection Under 35 USC §103(a) Over EP 1145707 (Iwai et al) in view of WO 01/00151 (Gavin et al.)

Claims 1, 3, 4 and 7-25 have been rejected under 35 USC §103(a) as being unpatentable over EP 1145707 (hereinafter "Iwai et al.") in view of WO 01/00151 (hereinafter "Gavin et al.")

Iwai et al. discloses compositions for external use comprising 0.01-20 wt% of a zinc compound, such as basic zinc carbonate, 0.01-20 wt% of a thiol compound and anionic surfactant. The Office Action has asserted that the basic zinc carbonate taught by Iwai et al. would have the same level of zinc lability as instantly claimed. The Office Action further asserts that Iwai et al. does not expressly teach a composition wherein the thiol compound is pyrithione, but that one of ordinary skill in the art would have been motivated to add zinc pyrithione, as suggested by Gavin et al., to the composition of Iwai et al. because Iwai et al. suggest adding thiol compounds to the composition by not specifically pyrithione and Gavin et al. cure this deficiency by teaching that zinc pyrithione is suitable for external compositons.

However, Applicants respectfully submit that a thiol (-SH) is structurally different from zinc pyrithione, and therefore the two compounds are not viewed by one of skill in the art as being interchangeable. It is readily known by one of skill in the art that a thiol is a compound that contains the functional group composed of a sulfur atom and a hydrogen atom (-SH). Thiols are organic compounds similar to an alcohol, but in which the oxygen atom has been replaced by a sulfur atom. Typically, thiols are liquids with penetration unpleasant smells. However, for pyrithione, sulfur is in a different oxidation state than a thiol, and is not classified as a thiol, but rather a thione. A thione and thiol are two different

chemical entities and function differently, as viewed by one of skill in the art. Accordingly, one of skill in the art would not be motivated to replace the thiol compound of Iwai et al. with the zinc pyrithione taught by Gavin et al.

Applicants respectfully direct attention to the Iwai et al disclosure on page 4, lines 23-26, wherein examples of zinc compounds include basic zinc carbonate and zinc pyrithione. Further, Examples 24A and 25A comprise zinc pyrithione. However, there are is nothing exemplified in Iwai et al. that comprises the combination of basic zinc carbonate and zinc pyrithione or nothing in Iwai et al. that would specifically motivate one of skill in the art combine basic zinc carbonate and zinc pyrithione.

Further, Iwai et al. in view of Gavin et al fails to teach or suggest wherein the ratio of a surfactant to zinc-containing layered material is greater than or equal to 2 to 1, as required in the present invention. Therefore, all of the claim limitations of the present invention are not taught or suggested by Iwai et al in view of Gavin et al.

In summary, it is submitted that the combination of Iwai et al in view of Gavin et al. fails to render the present claims unpatentable under 35 U.S.C. §103. A person skilled in the art would have no rationale or motivation to combine the teachings of Iwai et al with Gavin et al., as one of skill in the art would not be motivated to replace the thiol compound of Iwai et al. with the zinc pyrithione taught by Gavin et al. as with any probability of success.

Therefore, the claimed invention is unobvious and Applicants respectfully request that the rejection should be withdrawn.

Bhat et al (WO 96/25913) in view of Gavin et al (WO 01/00151)

Under 35 U.S.C. §103(a), Claims 1, 3, 4 and 7-25 are rejected as being unpatentable over Gavin et al (WO 01/00151) (hereinafter "Gavin et al.) in view of Bhat et al (WO 96/25913) (hereinafter "Bhat et al.). Applicant respectfully traverses this rejection in view of the arguments presented herein.

Gavin et al discloses topical compositions for the treatment of microbial infections on the skin or scalp which include a polyvalent metal salt of pyrithione and include a metal ion source. Bhat et al. discloses the use of monophasic zinc hydroxycarbonate as antimicrobial

agent in personal care products, particularly in such products which also contain a surfactant such as soap or a synthetic detergent.

The Office Action further has asserted Gavin et al. does not expressly teach a composition wherein the zinc salt is a zinc layered material, such as basic zinc carbonate. The Office action further asserts that it would have been obvious to one of ordinary skill in the art to add basic zinc carbonate, as suggested by Bhat et al., to the composition of Gavin et al. and produce the instant invention. It is the Office Action's position that the basic zinc carbonate taught by Bhat et al. would have the same level of zinc lability as the present invention.

However, Applicant submits that the references cited fail to establish a prima facie case of obviousness. Specifically, Gavin et al. in view of Bhat et al fails to teach or suggest all the claim limitations of the present invention. Gavin et al. in view of Bhat et al. fails to teach or suggest wherein wherein the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1. The Examiner has asserted the combination of Gavin et al. with Bhat's zinc hydroxcarbonate containing personal care product formulation would meet the zinc lability claim features.

However, as demonstrated in the table on page 31 of the present specification and the examples, the present invention has achieved efficacy with the technical rationale of a low level of basic zinc carbonate to high level of surfactant ratio. In contrast, if one of skill in the art were to look to Bhat et al., Bhat et al. exemplifies in Example 4 (a toothpaste) the exact opposite ratio of the present invention, a higher ratio of zinc hydroxycarbonate to surfactant ratio as compared to the present invention. Specifically, Bhat et al. teaches a ratio for a surfactant to zinc hydroxycarbonate of 2 to 3. This would clearly not lead one of skill in the art to the present invention ratio of surfactant to zinc-containing layered material greater than or equal to 2 to 1. As disclosed in the specification and presently amended claims, the present invention has found the components and ratios that result in the specified zinc lability. Gavin et al. in view of Bhat et al. does not provide the combination of the components and ratios that would lead one of skill in the art to the specified zinc lability. Further, one of skill the art would not be motivated to combine the teachings of Bhat et al. with Gavin et. al, as Bhat et al. is directed to a higher ratio of zinc component i.e. zinc

hydroxycarbonate to surfactant, when compared to Gavin et al. which teaches the presence of higher ratio of surfactants to zinc components.

If one of skill in the art were to combine the teaching of Gavin et al. with Bhat et al, there is no motivation to select the present invention's requirement of a ratio of surfactant to zinc-containing layered material greater than or equal to 2 to 1.

Therefore, Applicants find that Gavin et al. in view of Bhat et al. does not teach or suggest compositions having all of the claim limitations of the present invention, as defined in the present invention, and therefore fails to establish a prima facie case of obviousness.

Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejection under 102(b) and 103(a). Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1, 3-4 and 7-25 is respectfully requested.

Respectfully submitted,

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